

### **REMARKS**

Applicants thank the Examiner for reviewing the above-referenced application and respectfully request reconsideration of the claims in view of the arguments and amendments presented herein.

#### **Status of Claims**

Claims 1-7 and 11-23 are currently pending in the present application. Claims 1, 4, 5, and 7 have been amended as indicated above. Claims 8-10 have been cancelled. Claims 11-13 were previously withdrawn. New Claims 14-23 have been added. Accordingly, Claims 1-7 and 14-23 are presented for examination on the merits.

Support for amendment to Claim 1 is found throughout the application as filed. More particularly, support can be found, *inter alia*, at paragraphs [0018], [0056]-[0059], [0106]-[0109], [0111], [0112], Example 2, Table 2, Example 3, Table 3, and Table 4. Claims 4, 5, and 7 have been amended to comply with proper form of dependency of multiple dependent claims.

Support for new Claims 14-23 is found throughout the application as filed. More particularly, support can be found, *inter alia*, at paragraphs [0037]-[0055], [0059], [0080], [0101], and [0121] of the specification.

#### **Priority**

The instant application claims priority from U.S. Provisional Application Serial Number 60/455,585, filed on March 19, 2003. A verified English translation of the provision application 60/455,585 was filed on September 19, 2005. Support for amendment to Claim 1 is found throughout the provisional application, for example, at pages 7-11, 14, 17, 19, and 20; Examples 1, 2, and 3. Support for new Claims 14-23 is found, for example, at pages 11, 14, 17, 19, and 20 and Examples 1, 2, and 3.

#### **Drawings**

The Examiner in the Office Action Summary did not acknowledge acceptance of drawings filed on May 14, 2007. Applicants request that the Examiner acknowledge acceptance of those drawings.

**Rejections Under 35 U.S.C. § 112, ¶ 2**

**Claims 1-10**

The Examiner has rejected Claims 1-10 under 35 U.S.C. § 112, ¶ 2 as indefinite for failing to point out and distinctly claim the subject matter which Applicant regards as the invention. Although the Examiner has not explained precisely how the rejected claims fail to point out and distinctly claim the subject matter of the invention, Claim 1 has been amended to recite a step of analyzing the sample, wherein a higher level of core-2  $\beta$ 1,6-N-acetylglucosaminyltransferase (C2GnT) polypeptides compared to normal indicates an increased risk for cancer recurrence. The meaning of amended Claim 1 is thus discernible and clear to one of ordinary skill in the art. Thus, Claim 1 and claims dependent therefrom comply with 35 U.S.C. § 112, ¶ 2.

Furthermore, the Examiner states that Claim 9 is vague because it does not appear to further limit Claim 1. Applicants traverse, however this has been rendered moot by Applicants cancellation of Claim 9 in order to expedite allowance.

**Rejections Under 35 U.S.C. § 102(b) based on Fukuda**

**Claims 1-6 and 8-10**

The Examiner has rejected Claims 1-6 and 8-10 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,136,580 to Fukuda et al. ("Fukuda"). A claim is anticipated only if each and every element of the claim is expressly or inherently found in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP § 2131.

According to the Examiner, Fukuda discloses in Figure 8; column 15, lines 31-42; and column 20, Example IV, a method of detecting mammalian C2GnT-M and C2GnT-L polypeptides in human tissues and cancer cell lines using immunological procedures. Applicants disagree.

To the contrary, Figure 8 of Fukuda shows Northern analysis of C2GnT-M and C2GnT-L mRNA transcripts, not polypeptides, in tissues and cell lines. Currently amended Claim 1 recites detection of C2GnT polypeptides.

Example IV likewise shows the expression of C2GnT-M and C2GnT-L mRNA transcripts, not C2GnT polypeptides as recited in amended Claim 1. Furthermore, the C2GnT-M

and C2GnT-L mRNA transcripts of Example IV are detected by hybridization with cDNA fragments, not by immunological procedures.

In addition, Fukuda does not teach methods of detecting recurrence of cancer by measuring mRNA or protein levels of C2GnT-L. Although Column 15, lines 31-42 describe immunological detection of C2GnT-M generally, Fukuda does not disclose a method of detecting the prognosis of cancer in which elevated levels of C2GnT indicate an increased risk of cancer recurrence, as recited in the claims.

Because Fukuda does not teach each and every element recited in Claim 1, Fukuda does not anticipate Claim 1 or Claims 2-6, which depend from Claim 1. Claims 8-10 have been cancelled in order to advance prosecution. At least because each and every element recited in amended Claim 1 is not disclosed in the cited art, Claim 1 is not anticipated. Nor would dependent Claims 2-6 be anticipated for the same reasons. Accordingly, Applicants respectfully request the Examiner's rejections for anticipation be reconsidered and withdrawn.

**Rejections Under 35 U.S.C. § 102(b) based on Machida**

The Examiner has rejected Claims 1-4 and 8-10 under 35 U.S.C. § 102(b) as anticipated by Machida *et al.* (Cancer Research 61: 2226-31, March 1, 2001). As the Examiner indicated in the Office Action, Machida *et al.* discloses a method of detecting C2GnT mRNA. By contrast, amended claim 1 recites detecting C2GnT polypeptides.

Moreover, Machida does not discuss any correlation between the prevalence of C2GnT polypeptides and cancer recurrence, as recited in the claims. Machida teaches that expression of C2GnT is correlated with lymph node metastasis, but makes no mention of how detection of C2GnT polypeptides may play a role in determining recurrence of cancer in a subject.

Because Machida *et al.* do not describe each and every element recited in Claim 1, this reference cannot anticipate Claim 1 or Claims 2-4, which depend on Claim 1. Applicants therefore respectfully request the Examiner's rejections be reconsidered and withdrawn.

**Rejections Under 35 U.S.C. § 102(b) based on Shimodaira**

The Examiner has rejected Claims 1-4 and 8-10 under 35 U.S.C. § 102(b) as anticipated by Shimodaira *et al.* (Cancer Research 57: 5201-06, December 1, 1997). According to the

Examiner, Shimodaira *et al.* discloses a method of detecting carcinoma-associated expression of C2GnT in colorectal cancer specimens.

Shimodaira *et al.*, however, only discloses detection of C2GnT mRNA by RT-PCR to determine its association with invasion of colorectal cancer. Shimodaira *et al.* does not disclose detection of C2GnT polypeptides, nor how C2GnT polypeptides may play a role in determining recurrence of cancer in a subject as recited in amended Claim 1. For these reasons, Shimodaira, *et al.* fail to disclose each and every element of the rejected claims and thus do not anticipate Claims 1-4. Claims 8-10 have been cancelled, thus obviating their rejection. Applicants respectfully request that the rejection of Claims 1-4 based on Shimodaira *et al.* be withdrawn.

#### **Rejections Under 35 U.S.C. § 102(a) based on Ohyama**

The Examiner has rejected Claims 1-10 under 35 U.S.C. § 102(a) as anticipated by Ohyama *et al.* (Glycobiology 13(11): 864, November 2003). Applicants traverse and argue that Ohyama is not proper prior art to the present application as it was published after the effective filing date of the present application.

The present application claims priority from Provisional Application 60/455585 filed on March 13, 2003. As noted above, a verified English translation of the provision application 60/455,585 was filed on September 19, 2005. The provisional application fully supports the pending claims, and therefore Ohyama *et al.* is not prior art under 35 U.S.C. § 102(a) as it was not published prior to Applicants earliest filing date. Accordingly, Applicants respectfully request that the rejection of Claims 1-10 based on Ohyama *et al.* be withdrawn.

#### **Conclusion**

For the foregoing reasons, it is respectfully submitted that the rejections in the outstanding Office Action have been addressed and that the application is in condition for allowance.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this

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application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: 

Jeffrey J. Tung  
Registration No. 59,407  
Agent of Record  
Customer No. 20,995  
(619) 235-8550

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